

## **REMARKS**

Claims 1-27 were pending. Claims 5 and 6 are canceled as being directed to a non-elected invention. Claim 1 has been amended. Upon entry of these amendments, claims 1-4 and 7-27 will pending and under consideration.

No new matter has been added. Applicants reserve their right to prosecute the subject matter of any canceled claim, any amended claim, any withdrawn claim or any unclaimed subject matter in one or more related applications.

### **I. CLAIM AMENDMENTS**

Claim 1 has been amended to recite a stent comprising an effective amount of a c-Jun-N-terminal kinase Inhibitor and a nitric oxide release agent. Support for this amendment can be found, for example, on page 53, lines 10-11 of the specification as filed. No new matter has been added by this amendment. Entry of the presently made amendment is respectfully requested.

### **II. THE REJECTION UNDER 35 U.S.C. § 102**

Claims 1-3, 7-17, 22, 23 and 27 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Green *et al.* (WO 01/57022, hereinafter, "Green"). In particular, the Examiner has stated that the disclosure of Green meets the limitations of the instant claims (Office Action, page 3). This rejection is respectfully traversed. Reconsideration is respectfully requested in view of the amendment made to claim 1.

It is well established law that every limitation of a claim must appear in a single prior art reference for it to anticipate the claim. *Gechter v. Davidson* 116 F.3d 1454, 43 USPQ2d 1030 (Fed. Cir. 1997). It is respectfully submitted that Green does not teach each and every element of claims 1-3, 7-17, 22, 23 and 27, as explained below.

Amended claim 1 is drawn to a stent comprising an effective amount of c-Jun-N-terminal kinase (JNK) inhibitor and a nitric oxide release agent. Green does not teach a stent comprising a JNK inhibitor and a nitric oxide release agent and, accordingly, does not anticipate amended claim 1 nor claims 2, 3, 7-11 dependent therefrom. For the same reasons, claims 12-27, drawn to methods of making a stent of claim 1 or a kit comprising a stent of claim 1, are not anticipated by Green. Accordingly, Applicants respectfully submit that the rejection under 35 U.S.C. § 102(b) over Green should be withdrawn.

### **III. THE REJECTION UNDER 35 U.S.C. § 103 OVER BHAGWAT IN VIEW OF CHUDZIK**

Claims 1-4 and 7-27 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent Application Publication No. 2002/0103229 (“Bhagwat”) in view of U.S. Patent Application Publication No. 2002/0188037 (“Chudzik”). In particular, the Examiner has stated that it would have been obvious to a person skilled in the art at the time of the invention to use coated stents for sustained delivery of the JNK inhibitors (Office Action, page 4). Applicants respectfully disagree.

As acknowledged by the Examiner, Bhagwat does not teach a stent comprising a JNK inhibitor. Accordingly, Bhagwat also does not teach a stent comprising a JNK and a nitric oxide releasing agent.

Chudzik does not cure this deficiency. The Examiner stated that Chudzik was cited to show that acrylate coated stents provide controlled release of active agents (Office Action, page 5). Notably, Chudzik does not teach a nitric oxide release agent as part of the stents as claimed. Therefore, neither Bhagwat nor Chudzik, either alone or in combination, teach or suggest a stent comprising an effective amount of a JNK inhibitor and a nitric oxide release agent, or a method of making such stent, as instantly claimed. In addition, no reason has been provided as to why one of ordinary skill in the art would modify the teachings of Bhagwat and Chudzik to arrive at a stent comprising a JNK inhibitor and a nitric oxide release agent.

In *KSR*, the Supreme Court stated that “it can be important to *identify a reason* that would have prompted a person of ordinary skill...to combine the elements in the way the claimed new invention does.” *KSR International Co. v. Teleflex Inc.* 127 S.Ct. 1727, 167 L.Ed.2d 705, 75 USLW 4289, 82 U.S.P.Q.2d 1395 (2007)) (emphasis added); *see also* USPTO Memorandum (“it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.”).

Accordingly, Applicants respectfully submit that the pending claims are not *prima facie* obvious over Bhagwat in view of Chudzik and that the rejection under 35 U.S.C. § 103(a) over these references should be withdrawn.

**IV. THE REJECTION UNDER 35 U.S.C. § 103 OVER GREEN IN VIEW OF HARIHARAN OR THE MANUSCRIPT OF THE CLEVELAND HEART CLINIC**

Claims 1, 16-21 and 24-27 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Green *et al.* (WO 01/57022, hereinafter, “Green”) in view of Hariharan *et al.* (“Can Stent-Angioplasty be a Valid Alternative to Surgery when Revascularization is Indicated for Anomalous Origination of a Coronary Artery from the Opposite Sinus?” in Tex Heart Inst J 29(4):308-313, 2002), hereinafter, “Hariharan”) or “Treating Heart, Blood Vessels and Circulation”, Cleveland Clinic Heart Center, September 18, 2002 (hereinafter, “Cleveland paper”). In particular, the Examiner has stated that because Hariharan teaches that stenting can be done surgically and the Cleveland paper teaches that stenting can be done non-surgically, based on the combined teachings of the two references, one of ordinary skill in the art at the time of the invention would have a reasonable expectation of success in surgically or non-surgically implanting the medical device/stent of Green for the contemplated delivery of the composition of Green for treating conditions such as myocardial infarction (Office Action, page 6). Applicants respectfully disagree.

As discussed in Section II above, Green does not teach a stent comprising a JNK inhibitor and a nitric oxide release agent, as instantly claimed. Thus, Green fails to teach or suggest the essential elements of the claimed invention. Hariharan and the Cleveland paper fail to cure this deficiency. Furthermore, no reason has been provided as to why one of ordinary skill in the art would modify the teaching of Green, Hariharan and the Cleveland paper (either alone or in combination) in order to arrive at the claimed invention. *Id.*

Thus, Applicants respectfully submit that a *prima facie* case of obvious over Green in view of Hariharan or the Cleveland paper has not been established.

Accordingly, the rejection under 35 U.S.C. § 103(a) over these references should be withdrawn.

### Conclusion

Applicants respectfully request that the above remarks be entered in the present application file. No fee is estimated to be due in connection with this Response other than the fees due in connection with the Request for Continued Examination and Petition for Extension of Time; however, in the event that any additional fee is due, please charge the required fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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